REMARKS

In the Office Action mailed April 19, 2004:

Claims 48 and 49 were indicated to be allowable. Claim 11 was objected to as being dependent upon a rejected base claim but was indicated to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-8, 10, 12, 27, 31, 51-53, 55, 56, 57 and 58 were rejected under 35 U.S.C. 102(b) as anticipated by Lin et al. (U.S. Patent 5,591,139).

Claims 1-8, 10, 12, 25-27, 31, 32, 34, 36-37, 50-53 and 55 were rejected under 35 U.S.C. 102(e) as anticipated by Frazier et al.(WO 01/93930).

Claims 9, 13-15, 18 and 20-24 were rejected under 35 U.S.C. 103(a) as unpatentable over Lin et al. in view of Say et al.

Claims 9 and 13-15 were rejected under 35 U.S.C. 103(a) as unpatentable over Frazier et al. in view of Say et al.

Claims 16 and 17 were rejected under 35 U.S.C. 103(a) as unpatentable over Lin et al. in view of Say et al, as applied to claims 9,13-15, 18, and 20-24, further in view of Meade et al.

Claims 16 and 17 were also rejected under 35 U.S.C. 103(a) as unpatentable over Frazier et al. in view of Say et al, as applied to claims 9,13-15, 18, and 20-24, further in view of Meade et al.

Claim 19 was rejected under 35 U.S.C. 103(a) as unpatentable over Lin et al. in view of Say et al, as applied to claims 9,13-15, 18, and 20-24, further in view of Kim et al.

Claim 25 was rejected under 35 U.S.C. 103(a) as unpatentable over Lin et al. in view of Smart et al. (US 5,801,057).

Claims 34 and 36 were rejected under 35 U.S.C. 103(a) as unpatentable over Lin et al. in view of Kim et al.

Claim 59 was rejected under 35 U.S.C. 103(a) as unpatentable over Lin et al. in view of the Smart et al article entitled "The use of Silicon Microfabrication Technology in Painless Blood Glucose Monitoring."

Claim 59 was rejected under 35 U.S.C. 103(a) as unpatentable over Frazier et al. in view of the Smart et al article entitled "The use of Silicon Microfabrication Technology in Painless Blood Glucose Monitoring."

INTERVIEW SUMMARY

An interview was conducted on July 15, 2004 between the Examiner and attorney Joshua D. Isenberg and agent Margaret Smart. A power of attorney appointing Mr. Isenberg and Ms. Smart was submitted by facsimile on July 15, 2004. A copy of the power of attorney is attached.

In the course of the interview, the Examiner indicated that the amendments to claim 1 overcome the 35 USC 102 rejections based on Lin and Frazier. With respect to claim 50, the Examiner indicated that there was no showing in the prior art of at least one biosensor on each side of the substrate. The Examiner also indicated that declaration by Wilson Smart submitted in response to the rejection of claim 51 under 35 USC 103 appeared to overcome that rejection. However, the Examiner further indicated that he would have to consider the declaration further. The Examiner also indicated that the language of claim 57 as presently amended would be acceptable and sufficient to overcome the 35 USC 102 rejection based on Lin. In addition, the Examiner indicated that claim 58 would be allowable based on its dependence from allowed claim 48. The Examiner also indicated that the claim amendments raise new issues for consideration.

CLAIM AMENDMENTS

Claims 55, 56, 58 and 59 have been cancelled.

To expedite prosecution, claim 1 has been amended to recite that the substrate is made of single-crystal silicon and that the body portion and microprobe portions are made entirely by the silicon substrate. Support for these features can be found in the specification e.g., as appears at page 5, lines 6-7 (see paragraphs 0014 and 0107 in the published version of the application, US Patent Publication 2002/0137998) and also at FIGs. 1A, 1B, 2A, 2B, 4A, 4B. As such, the applicants submit that no new matter has been entered with these amendments.

To provide a desired scope of claim coverage, claim 2 has been amended to recite that the width of the microprobe tapers smoothly over substantially all of its length. Support for this feature can be found in the original specification at FIGs. 1A and 2A. As such, the applicants submit that no new matter has been entered with these amendments.

To expedite prosecution, claim 11 has been rewritten in independent form as suggested by the examiner. As such, the applicants submit that no new matter has been entered with these amendments.

To expedite prosecution, claim 50 has been amended to recite that multiple biosensors are disposed on both sides of the silicon substrate. Support for this feature can be found in

claim 50 as originally filed. As such, the applicants submit that no new matter has been entered with this amendment.

To expedite prosecution, claim 51 has been amended to recite that the microprobe portion tapers "*smoothly* in width along the *entire* X length dimension converging from a larger Y width dimension at the body end to a smaller Y width dimension at the penetration end" (emphasis added). Support for this feature can be found in the specification at FIG. 1A and FIG. 2A. As such, no new matter has been added with this amendment.

To obtain a desired scope of claim coverage, the applicants have amended claim 52 and added new claim 60, which depends from claim 5, to recite that the Y width of the microprobe portion tapers from about 200 micrometers at the body end to about 30 micrometers at a point between a beginning of the penetration end and a termination of the penetration end. Support for this feature can be found in the original specification as follows. Page 11, lines 2-5 (Paragraph 0095) and claim 5 as originally filed recite that the probe tapers from 200 micrometers to 30 micrometers "at the penetration end." FIGs. 1A and 2A show the penetration end terminating at a point. The drawings also show the penetration ends 14P and 16P include the last section of the probe, not just the point. The applicants submit that "at the penetration end" reasonably interpreted means "at some location between where the penetration end begins and where it ends" based on what is shown in FIG. 1A and FIG. 2A. As such, no new matter has been added with these amendments.

To expedite prosecution, claim 57 has been rewritten in independent form and to recite that "substantially the entire area of at least the penetration end including the tip has a substantially equal thickness in the Z direction that is less than the body portion". Support for this feature can be found in the specification at page 11, line 15 (paragraph 0095) and FIG. 3B. As such, no new matter has been added with these amendments

To expedite prosecution, the applicants have cancelled claim 59 and incorporated the features of claim 59 into claim 51. Since claim 59 originally depended from claim 51, the applicants submit that no new matter has been added with this amendment.

CLAIM REJECTIONS

35 USC 102

The Applicant submits that all rejections of claims 55, 56, 58 and 59 are moot in view of their cancellation.

Claims 1-8,10, 12. 27. 31. 37, 51-53, 55, 56, 57 and 58 were rejected under 35 U.S.C. 102(b) as being anticipated by Lin et al. (US 5,591,139).

Claim 1 has been amended to indicate that the microprobe is made entirely from a single crystal substrate. The Applicant submits that Lin, by contrast, specifically teaches that "there is no single crystal silicon at the tip region" (see col. 4, lines 29-32 of Lin). As such, Lin does not teach or suggest, and in fact teaches away from, a microprobe made entirely from silicon as set forth in claim 1. , Furthermore, the Examiner's comments in the Office Action of April 19, 2004 suggest that Lin does not teach such a feature. As such, Lin does not anticipate claim 1. Therefore, these claims define an invention suitable for patent protection.

Furthermore, claims 2-8, 10, 12, 27, 31, 37 depend from claim 1 and recite additional features therefor. As such, and for the same reasons set forth above, the applicants submit that these dependent claims define an invention suitable for patent protection.

In addition, claim 51 has been amended to recite that the microprobe portion tapers "*smoothly* in width along the *entire* X length dimension converging from a larger Y width dimension at the body end to a smaller Y width dimension at the penetration end" (emphasis added). Lin by contrast shows the shaft 14 having no taper, except at the tip region 86. As such, Lin does not teach all the limitations of claim 51. Therefore claim 51 defines an invention suitable for patent protection. Furthermore, the applicants submit that claims 52-53 are allowable by virtue of their dependence from claim 51.

In addition, claim 57 has been amended to recite that "substantially the entire area of at least the penetration end including a tip has a substantially equal thickness in the Z direction that is less than the body portion" as described above. Lin, by contrast, teaches "The tip region 86 is formed at an angle θ of approximately 45° to the plane of the needle shaft 14, to form a sharp triangular tip 87" (see column 4, lines 10-12). Furthermore, Fig. 2B of Lin clearly shows an abrupt change in thickness of the tip region 86 in the vicinity of the triangular tip 87. Thus Lin clearly does not teach, and in fact teaches away from a penetration end including a tip having "a substantially equal thickness in the Z direction that is less than the body portion" as presently recited in claim 57. As such, Lin does not teach all the limitations of claim 57. Therefore claim 57 defines an invention suitable for patent protection. Furthermore, the applicants submit that claims 52-53 are allowable by virtue of their dependence from claim 57.

Furthermore, the applicants submit that the rejection of claim 58 is improper since claim 58 depends from claim 48, which has been allowed.

The Examiner has also rejected claims 1-8, 10, 12, 25-27, 31, 32, 34, 36-37, 50-53, 55 and 58 under 35 U.S.C. 102(e) as being anticipated by Frazier et al.(WO 01/93930).

The applicants submit that Frazier et al. does not teach or suggest that a microprobe portion and a body portion formed entirely by a single crystal substrate. Instead, at page 8, lines 7-14, Frazier et al. state that the microneedle can be fabricated by micromachining techniques from a long list of materials including silicon. Silicon is a non-metallic element that exists in both crystalline and amorphous forms, as described in Hawley's Condensed Chemical Dictionary, John Wiley & Sons, page 992 (hereinafter Hawley). A copy of the reference is attached for the Examiner's convenience. Hawley states, inter alia that "[c]rystalline silicon is made commercially in an electric furnace by heating SiO_2 with carbon followed by zone refining."

Frazier et al. describe only one method of microneedle fabrication at (page 13, line 9 page 15, line 5), in which the microneedle base, sides, and top are formed of material deposited in sequence. If the disclosed fabrication method could be modified to use silicon, the deposited silicon could be either polycrystalline or amorphous silicon, but could not be single-crystal silicon. The applicant submits that the method used to produce the array of fragile 10-25 micrometer-long microneedles disclosed by Ginaven (cited by Frazier et al at page 2, lines) cannot produce microneedles of the size required by Lin et al., Frazier et al., or applicant, nor could biosensors be integrated thereupon.

At page 2, lines 14-16, Frazier et al. cite Lin et al. (US 5,591,139) as providing a reference in which "silicon-based microneedles are fabricated using integrated circuit processes." Further, at page 15, lines 20-22, Frazier et al. incorporate by reference a disclosure from Lin et al. "of a procedure for fabricating a microneedle with on-chip devices." The method for fabricating a microneedle disclosed in Lin et al. may be suitable for fabricating a microneedle of the type disclosed in Frazier et al. Such a microneedle will have the limitations discussed above with regard to the Lin et al. reference, namely that "there is no single crystal silicon at the tip region" (US 5,591,139 Col. 4, lines 29-32). By incorporating these teachings, Frazier does not teach, and teaches away from, the invention as set forth in claims 1, which recites that the body portion and microprobe portion (including the penetration end) are all formed by the same single crystal silicon substrate.

Furthermore, nowhere do Frazier et al. state that the microneedle itself is made of single-crystal silicon, nor that it is entirely made from a single-crystal silicon substrate as is applicants' microprobe, and as is set forth in amended Claim 1 and in claims 55 and 56. Instead, Frazier et al. specifically teaches forming microneedles 28 from a metal such as palladium (see p 15 ,line 25 to p. 15, line 21 and FIGs. 8A-8F) and that the substrate 26 is made from silicon (see p. 13, lines 10-12). Frazier et al. therefore do not anticipate claim 1 as it presently stands in the application.

Furthermore, claims 2-8, 10, 12, 25-27, 31, 32, 34, 36-37 depend from claim 1 and recite additional features therefor. As such, and for the same reasons set forth above, the applicants submit that these dependent claims define an invention suitable for patent protection.

In addition, claim 50 has been amended to recite that multiple biosensors are disposed on both sides of the silicon substrate. The applicants submit that Frazier et al. disclose multiple biosensors on one side of the silicon substrate, but not both sides (see e.g., FIGs. 1A-7B of Frazier et al.). As such, Frazier et al. do not anticipate the invention as set forth in claim 50. Therefore, claim 50 defines an invention suitable for patent protection.

Furthermore, claim 51 has been amended to recite that the microprobe portion tapers "*smoothly* in width along the *entire* X length dimension converging from a larger Y width dimension at the body end to a smaller Y width dimension at the penetration end" as described above. Frazier et al. by contrast shows microneedles 10, 21 and 24 having no taper, except at a tip region (see Fig. 1A, 2A and 2B). As such, Frazier et al. does not teach all the limitations of claim 51. Therefore claim 51 defines an invention suitable for patent protection. Furthermore, the applicants submit that claims 52-53 are allowable by virtue of their dependence from claim 51.

35 USC 103

The applicant submits that the rejections of:
claims 9, 13-15, 18 and 20-24 over Lin et al. in view of Say et al.,
claims 9 and 13-15 under 35 U.S.C. 103(a) over Frazier et al. in view of Say et al.,
claims 16 and 17 Lin et al. in view of Say et al in further view of Meade et al.,
claim 19 over Lin et al. in view of Say et al, in further view of Kim et al.,
claim 25 over Lin et al. in view of Smart et al. (US 5,801,057), and
the rejection of claims 34 and 36 over Lin et al. in view of Kim et al.

are all overcome in view of the amendments to claim 1. Specifically, neither Lin et al, nor Frazier et al., nor Say et al. nor Meade et al., nor Kim teaches or suggests a microprobe portion and body portion formed entirely from a single-crystal silicon substrate as set forth above. As such, no combination these references teaches or suggests all the features of claim 1 and a prima facie case is not present with respect to the rejected claims by virtue of their dependence from claim 1.

Claim 59 was rejected under 35 U.S.C. 103(a) as unpatentable over Lin et al. in view of the Smart et al article entitled "The use of Silicon Microfabrication Technology in Painless Blood Glucose Monitoring." The Examiner has similarly rejected claim 59 under 35 U.S.C. 103(a) as unpatentable over Lin et al. in view of the Smart et al article entitled "The use of Silicon Microfabrication Technology in Painless Blood Glucose Monitoring." As set forth above, claim 59 has been canceled and claim 51 has been amended to incorporate dependent Claim 59. To expedite prosecution an affidavit under 37 CFR 1.132 by inventor Wilson Smart is submitted in response to the Examiner's rejection of the subject matter of Claim 59, which is now incorporated into claim 51. It is respectfully requested that this Affidavit be considered in that this is the first opportunity for its submission. This affidavit establishes that the subject matter of claim 51 was invented by the two authors of the Smart et al. article who are also listed as inventors of the present application. The third inventor, Eugene Orloff, did not invent the subject matter of claim 51 since it was conceived and several tapered cantilevers were fabricated before he began working with the other two inventors. As such, claim 51 does not represent the work of another. Hence, the Smart et al. article is not available as prior art under a rejection based on 35 USC 102(a)/103.

CONCLUSION

In view of the foregoing, applicants believe that all of the claims are now in condition for allowance. The applicants therefore respectfully request reconsideration of the application and a notice of allowance. If for any reason the Examiner believes any of the claims are not in condition for allowance, he is encouraged to phone the undersigned at (510) 896-8328 so that any remaining issues may be resolved.

Respectfully submitted,

Joshua D. Isenberg

Date: July 19, 2004

Joshua D. Isenberg
(Reg. No. 41,088)

OFFICIAL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of)
WILSON SMART)
Application Serial No.: 09/816,472) Group Art Unit: 3736
Filed: March 26, 2001) Examiner: Robert Nasser
For: SILICON MICROPROBE WITH INTEGRATED BIOSENSOR)

DECLARATION UNDER 37 CFR 1.132

I, Wilson Smart, declare and state that:

1. I am one of the inventors of the subject matter of claim 51 the above-identified patent application.

2. I am the President and Chairman of the Board of Kumetrix, Inc., the assignee of the invention that is the subject of the above-identified application.

3. Kumar Subramanian and I are the authors of the article entitled "The Use of Silicon Microfabrication Technology in Painless Blood Glucose Monitoring" in Diabetes Technology & Therapeutics, Volume 2, Number 4, 2000 (the "Smart et al. Article").

4. Eugene Orloff, who is listed as an inventor in the above-referenced patent application was not an inventor of the subject matter presently in claim 51 based on the following facts:

   a. Kumar Subramanian and I conceived of tapered cantilevers for a microprobe device of the type set forth in claim 51 before Eugene Orloff was hired by Kumetrix.
   b. As a result of this conception, cantilevers of different shapes, including tapered cantilevers were designed, mask drawings made, and several tapered cantilevers fabricated before Eugene Orloff was hired by Kumetrix.

5. The Smart et al. Article was published less than one year before the filing date of the present application.

6. I declare further that all of the statements herein of my own knowledge are true; and all statements made on knowledge and belief are believed true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the present application and any patent issuing thereon.

Date: 14 July 2004 Wilson Smart
Wilson Smart

Application Serial No. 09/816,472
Attorney Docket No. 060879-0005

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being filed with the United States Patent and Trademark Office by facsimile transmission on July 19, 2004 to facsimile telephone number 703 - 872 -9306

Joshua D. Isenberg 41,088 (Reg. No.)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
SMART et al.

Serial No.: 09/816,472

Filed: March 26, 2001

For: SILICON MICROPROBE WITH INTEGRATED BIOSENSOR

Group Art Unit: 3736

Examiner: Robert Nasser

Attorney Docket No.: 060879-0005

REVOCATION AND POWER OF ATTORNEY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Wilson Smart, President of Kumetrix, Inc., owner of the entire right, title and interest in, to and under the invention described and claimed in the above-identified patent application hereby revoke all previous powers of attorney and appoint Joshua D. Isenberg (Reg. No. 41,088) of JDI Patent , whose address is 204 Castro Lane, Fremont, CA 94539 and Margaret M. Smart (Reg. No. 55,626) of Kumetrix, Inc. whose address is 29524 Union City Boulevard, Union City, CA 94587.

Please direct all future correspondence to Kumetrix, Inc. at the above address and direct all telephone calls to Joshua D. Isenberg at (510) 896-8328..

Respectfully submitted.

Date: 14 JULY 2004 By: _____

Wilson Smart
President
KUMETRIX, INC.
29524 Union City Boulevard
Union City, CA 94587

Hawley's

Condensed Chemical Dictionary

Fourteenth Edition

Revised by
Richard J. Lewis, Sr.

JOHN WILEY & SONS, INC.

terial for high-temperature mortars.
See "Aerosil"; "Cab-O-Sil."

silica, fused. (amorphous quartz).
CAS: 60676-86-0. O_2Si.
Properties: Mw 60.09. Made up of spherical submicroscopic particles under 0.1 micron in size.
Hazard: TLV: 0.1 mg/m³ (Respirable Fraction).
Use: Concrete, grouts, mortars, elastomers, refractory and coating applications.
See silica; quartz, fused.

silica gel.
CAS: 7631-86-9. (silica, amorphous hydrated; silicic acid). A regenerative adsorbent consisting of amorphous silica. Noncombustible.
Derivation: From sodium silicate and sulfuric acid.
Grade: Commercial grades capable of withstanding temperatures up to 260–315C are supplied in the following mesh sizes: 3–8, 6–16, 14–20, 14–42, 28–200, and through 325.
Hazard: TLV: TWA (nuisance particulate) 10 mg/m³ of total dust (when toxic impurities are not present, e.g., quartz <1%).
Use: Dehumidifying and dehydrating agent, air-conditioning, drying of compressed air and other gases and liquids such as refrigerants and oils containing water in suspension, recovery of natural gasoline from natural gas, bleaching of petroleum oils, catalyst and catalyst carrier, chromatography, anticaking agent in cosmetics and pharmaceuticals, in waxes to prevent slipping, in dietary supplements.
See silicic acid; "Britesorb" *[PQ]*.

"Silic AR" *[Mallinckrodt]*. TM for silica-gel-based formulations suitable for various chromatographic applications. The numerical suffixes indicate the approximate pH of a 10% slurry. Letters F, G, or GF indicate that the product contains a fluorescent material, gypsum binder, or both. "TLC" indicates suitability for thin-layer chromatography.

silicate. Any of the widely occurring compounds containing silicon, oxygen, and one or more metals with or without hydrogen. The silicon and oxygen may combine with organic groups to form silicate esters. Most rocks (except limestone and dolomite) and many mineral compounds are silicates. Typical natural silicates are gemstones (except diamond), beryl, asbestos, talc, clays, feldspar, mica, etc. Portland cement contains a high percentage of calcium silicates. Best known of the synthetic (soluble) silicates is sodium silicate (water glass).
Hazard: (Natural silicate dusts) Toxic by inhalation.
Use: Fillers in plastics and rubber, paper coatings, antacids, anticaking agents, cements.

silicate garden. The irregular, colored, tubular growths formed in dilute aqueous silicate solutions by dropping water solutions of heavy metal salts into it.

silicic acid. (hydrated silica).
CAS: 7699-41-4. $SiO_2 \cdot nH_2O$. The jellylike precipitate obtained when sodium silicate solution is acidified. The proportion of water varies with the conditions of preparation and decreases gradually during drying and ignition, until relatively pure silica remains. During drying the jelly is converted to a white, amorphous powder or lumps.
Use: Laboratory reagent and reinforcing agent in rubber.
See silica gel.

silicochloroform. See trichlorosilane.

silicol. Silicic oxide casein metaphosphate.

silicomanganese. Alloys consisting principally of manganese, silicon, and carbon.
Use: Low-carbon steel in which silicon is not objectionable. Silicon manganese steels are used for springs and high-strength structural steels.
See ferromanganese.

silicomolybdic acid. See 12-molybdosilicic acid.

silicon. (silicon powder, amorphous).
CAS: 7440-21-3. Si. Nonmetallic element Atomic number 14, group IVA of the periodic table, aw 28.086, valence = 4, three stable isotopes. It is the second most abundant element (25% of the earth's crust) and is the most important semiconducting element; it can form more compounds than any other element except carbon.
Properties: Dark-colored crystals (the octahedral form in which the atoms have the diamond arrangement). The amorphous form is a dark-brown powder (see silicon, amorphous). D 2.33, mp 1410C, bp 2355C, Mohs hardness 7, dielectric constant 12, coordination number 6. Soluble in a mixture of nitric and hydrofluoric acids and in alkalies; insoluble in water, nitric acid, and hydrochloric acid. Combines with oxygen to form tetrahedral molecules in which one silicon atom is surrounded by four oxygen atoms. In this respect it is similar to carbon. It is also capable of forming –Si=Si– double bonds in organosilicon compounds.
Occurrence: Does not occur free in nature but is a major portion of silica and silicates (rocks, quartz, sand, clays, etc.).
Derivation: Crystalline silicon is made commercially (96–98% pure) in an electric furnace by heating SiO_2 with carbon, followed by zone refining. It can be purified to 99.7% by leaching. The ultrapure semiconductor grade (99.97%) is obtained by reduction of purified silicon tetrachloride or trichlorosilane with purified hydrogen; the silicon is deposited on hot filaments (800C) of tantalum or tungsten. In a one-step method, sodium fluorosilicate is reacted with sodium, the heat produced being sufficient to form silicon tetrafluoride; this, when reacted with sodium, yields high-purity silicon and sodium fluo-